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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,967	03/28/2000	Bruno Guy	50019/006001	7903

7590 12/20/2001

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/403,967**

Applicant(s)  
**Guy et al**

Examiner  
**Portner**

Art Unit  
**1645**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 24, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-58 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 29-58 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

Claims 29-58 are pending.

### *Election/Restrictions*

1. Applicant's election of Group I, species 2 in Paper No. 9 is acknowledged. The election was made without traverse, and stated to encompass a method of inducing an immune response and to include claims 39, 43, 44, 46-57.

It is the position of the examiner that Applicant made a bona fide attempt to respond to the election/restriction requirement made in paper number 6, but Group I was not defined to be directed to method claims, but to composition claims and the claims in Group I are 29-38 not claims 39, 43, 44, 46-57.

2. The reply filed on August 24, 2001 is not fully responsive to the prior Office action because of the following omission(s) or matter(s): The Group and the claims do not correspond to one another. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

The Election/Restriction is for Applicant's convenience set forth below.

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3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 29-38, drawn to compositions that comprise an immunogenic agent and a compound that promotes induction of a T-1 helper 1-type immune response.

Group II, claim(s) 39-57, drawn to a method of stimulating a T-helper 1-type immune response directed against *Helicobacter*.

Group III, claim(s) 58, drawn to a method of inducing a T-helper 1-type immune response against *Helicobacter* in a patient through administering any compound that induces a T helper 1-type immune response against *Helicobacter* in a patient.

4. The inventions listed as Groups I,II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: .

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**Group I:** 1. Saponin together with *H.pylori* antigen

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2. Cationic lipids together with H.pylori antigen;
3. A glycolipopeptide together with H.pylori antigen;
4. A combination of a saponin and a cationic lipid.

**Group II:** 1. A method of inducing an immune response through administering a saponin together with H.pylori antigen

2. A method of inducing an immune response through administering a cationic lipid together with H.pylori antigen;

3. A method of inducing an immune response through administering a glycolipopeptide together with H.pylori antigen;

4. A method of inducing an immune response through administering a combination of a saponin and a cationic lipid together with H.pylori antigen.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

Group I: Species 1: claims 29 and 32

Species 2: claims 29, 33 and 34

Species 3: claims 29, 30 and 35

Species 4: claim 31

The following claim(s) are generic: 36-38.

Group II: Species 1: claims 39 and 42

Species 2: claims 39, 43 and 44

Species 3: claims 39, 40 and 45

Species 4: claim 41

The following claim(s) are generic: 46-57.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: structurally saponins, cationic lipids and glycolipopeptides are structurally differ and therefore do not share a common special technical feature and the prior art, WO96/31235, teaches *Helicobacter pylori* compositions together with one of the claimed adjuvants. The claimed invention(s) are not so linked as to define a special technical that furthers the art; therefore restriction is considered proper.

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8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. General Observations: The application lacks an abstract and a Brief Description of the Drawings.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

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The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

December 17, 2001

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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